

One Hundred Third Congress
of the
United States of America

AT THE FIRST SESSION

*Begun and held at the City of Washington on Tuesday,
the fifth day of January, one thousand nine hundred and ninety-three*

An Act

To clarify and revise the small business exemption from the nutrition labeling requirements of the Federal Food, Drug, and Cosmetic Act, and for other purposes.

*Be it enacted by the Senate and House of Representatives of
the United States of America in Congress assembled,*

SECTION 1. SHORT TITLE.

This Act may be cited as the “Nutrition Labeling and Education Act Amendments of 1993”.

SEC. 2. SMALL BUSINESS EXEMPTION.

(a) APPLICATION OF EXISTING EXEMPTION.—

(1) BEFORE MAY 8, 1995.—Before May 8, 1995, the exemption provided by section 403(q)(5)(D) of the Federal Food, Drug, and Cosmetic Act shall be available in accordance with the regulations of the Secretary of Health and Human Services published at 21 C.F.R. 101.9(j)(1)(i)(1993).

(2) AFTER MAY 8, 1995.—After May 8, 1995, the exemption provided by section 403(q)(5)(D) of the Federal Food, Drug, and Cosmetic Act shall only be available with respect to food when it is sold to consumers.

(b) NEW EXEMPTION.—Section 403(q)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)) is amended by redesignating clauses (E) and (F) as clauses (F) and (G), respectively, and by adding after clause (D) the following:

“(E)(i) During the 12-month period for which an exemption from subparagraphs (1) and (2) is claimed pursuant to this subclause, the requirements of such subparagraphs shall not apply to any food product if—

“(I) the labeling for such product does not provide nutrition information or make a claim subject to paragraph (r),

“(II) the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 100 full-time equivalent employees,

“(III) such person provided the notice described in subclause (iii), and

“(IV) in the case of a food product which was sold in the 12-month period preceding the period for which an exemption was claimed, fewer than 100,000 units of such product were sold in the United States during such preceding period, or in the case of a food product which was not sold in the 12-month period preceding the period for which such exemption is claimed, fewer than 100,000 units of such product are reasonably anticipated to be sold in the United States during the period for which such exemption is claimed.

“(ii) During the 12-month period after the applicable date referred to in this sentence, the requirements of subparagraphs (1) and (2) shall not apply to any food product which was first introduced into interstate commerce before May 8, 1994, if the labeling for such product does not provide nutrition information or make a claim subject to paragraph (r), if such person provided the notice described in subclause (iii), and if—

“(I) during the 12-month period preceding May 8, 1994, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 300 full-time equivalent employees and fewer than 600,000 units of such product were sold in the United States,

“(II) during the 12-month period preceding May 8, 1995, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 300 full-time equivalent employees and fewer than 400,000 units of such product were sold in the United States, or

“(III) during the 12-month period preceding May 8, 1996, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 200 full-time equivalent employees and fewer than 200,000 units of such product were sold in the United States.

“(iii) The notice referred to in subclauses (i) and (ii) shall be given to the Secretary prior to the beginning of the period during which the exemption under subclause (i) or (ii) is to be in effect, shall state that the person claiming such exemption for a food product has complied with the applicable requirements of subclause (i) or (ii), and shall—

“(I) state the average number of full-time equivalent employees such person employed during the 12 months preceding the date such person claims such exemption,

“(II) state the approximate number of units the person claiming the exemption sold in the United States,

“(III) if the exemption is claimed for a food product which was sold in the 12-month period preceding the period for which the exemption was claimed, state the approximate number of units of such product which were sold in the United States during such preceding period, and, if the exemption is claimed for a food product which was not sold in such preceding period, state the number of units of such product which such person reasonably anticipates will be sold in the United States during the period for which the exemption was claimed, and

“(IV) contain such information as the Secretary may require to verify the information required by the preceding provisions of this subclause if the Secretary has questioned the validity of such information.

If a person is not an importer, has fewer than 10 full-time equivalent employees, and sells fewer than 10,000 units of any food product in any year, such person is not required to file a notice for such product under this subclause for such year.

“(iv) In the case of a person who claimed an exemption under subclause (i) or (ii), if, during the period of such exemption, the number of full-time equivalent employees of such person exceeds the number in such subclause or if the number of food products sold in the United States exceeds the number in such subclause, such exemption shall extend to the expiration of 18 months after

the date the number of full-time equivalent employees or food products sold exceeded the applicable number.

“(v) For any food product first introduced into interstate commerce after May 8, 2002, the Secretary may by regulation lower the employee or units of food products requirement of subclause (i) if the Secretary determines that the cost of compliance with such lower requirement will not place an undue burden on persons subject to such lower requirement.

“(vi) For purposes of subclauses (i), (ii), (iii), (iv), and (v)—

“(I) the term ‘unit’ means the packaging or, if there is no packaging, the form in which a food product is offered for sale to consumers,

“(II) the term ‘food product’ means food in any sized package which is manufactured by a single manufacturer or which bears the same brand name, which bears the same statement of identity, and which has similar preparation methods, and

“(III) the term ‘person’ in the case of a corporation includes all domestic and foreign affiliates of the corporation.”.

SEC. 3. TECHNICAL AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) REFERENCE.—Whenever in this section an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

(b) SECTION 201.—Paragraphs (w), (x), (y), (z), (aa), (bb), (cc), (dd), (ee), and (ff) of section 201 (21 U.S.C. 321) are redesignated as paragraphs (v), (w), (x), (y), (z), (aa), (bb), (cc), (dd), and (ee) respectively.

(c) SECTION 301.—Section 301 (21 U.S.C. 331) is amended—

(1) in subsection (j), by striking out “721, or 708” and inserting in lieu thereof “708, or 721”; and

(2) in subsection (s), by striking out “412(d)” and inserting in lieu thereof “412(e)”.

(d) SECTION 302.—Section 302 (21 U.S.C. 332) is amended—

(1) in subsection (a), by striking out “, and subject to” and all that follows through “381),” and

(2) in subsection (b), by striking out the second sentence.

(e) SECTION 303.—Section 303 (21 U.S.C. 333) is amended by redesignating the second subsection (e) and subsection (f) as subsections (f) and (g), respectively.

(f) SECTION 304.—Section 304 (21 U.S.C. 334) is amended—

(1) in subsection (a)(1), by striking out “: *Provided, however,* That no” and inserting in lieu thereof a period and “No”, and

(2) in subsection (d)(1)—

(A) by striking out “: *Provided, That after*” and inserting in lieu thereof a period and “After”,

(B) by striking out “: *Provided, however, That the*” and inserting in lieu thereof a period and “The”,

(C) by striking out “: *And provided further, That where*” and inserting in lieu thereof a period and “Where”, and

(D) by striking out “the foregoing proviso” and inserting in lieu thereof “the preceding sentence”.

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(g) SECTION 307.—Section 307(b)(3)(A) (21 U.S.C. 337(b)(3)(A)) is amended by striking out “Act” and inserting in lieu thereof “section”.

(h) SECTION 401.—Section 401 (21 U.S.C. 341) is amended by striking out “and/or reasonable standards of fill of container: *Provided*, That no” and inserting in lieu thereof “or reasonable standards of fill of container. No”.

(i) SECTION 402.—Section 402 (21 U.S.C. 342) is amended—

(1) by striking out “; or” at the end of subparagraphs (1) and (2) of paragraph (a) and inserting in lieu thereof a period and by striking out “if it” at the beginning of subparagraph (3) of such paragraph and inserting in lieu thereof “If it”,

(2) in paragraph (d)(1), by striking out “: *Provided*, That this clause” and inserting in lieu thereof “, except that this subparagraph”, and

(3) in paragraph (d)(3), by striking out “: *Provided*, That this clause” and inserting in lieu thereof “, except that this subparagraph” and by striking out “: *And provided further*, That the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this clause” and inserting in lieu thereof “, except that the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this subparagraph”.

(j) SECTION 403.—Section 403 (21 U.S.C. 343) is amended—

(1) in paragraph (e), by striking out “: *Provided*, That” and inserting in lieu thereof “, except that”,

(2) in paragraph (i), by striking out “, other than those sold as such” and inserting in lieu thereof “unless sold as spices, flavorings, or such colors” and by striking out “: *Provided*, That, to the extent” and inserting in lieu thereof a period and “To the extent”,

(3) in paragraph (k), by striking out “: *Provided*, That” and inserting in lieu thereof “, except that”,

(4) in paragraph (l), by striking out “: *Provided*, however, That” and inserting in lieu thereof “, except that”,

(5) in paragraph (r)(1)(B), by striking out “5(D)” and inserting in lieu thereof “(5)(D)”, and

(6) in paragraph (r)(4)(B), by striking out “subsection” and inserting in lieu thereof “paragraph”.

(k) SECTION 408.—Section 408 (21 U.S.C. 346a) is amended—

(1) in subsection (a)(1), by striking out “Secretary of Health and Human Services” and inserting in lieu thereof “Administrator of the Environmental Protection Agency (hereinafter in this section referred to as the ‘Administrator’)”,

(2) in subsection (d)(5), by striking out “section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c))” and inserting in lieu thereof “section 556(c) of title 5, United States Code”,

(3) in subsection (l), by striking out “It the event” and inserting in lieu thereof “In the event”,

(4) in subsection (n), by striking out “of the Federal Food, Drug, and Cosmetic Act”,

(5) in subsection (o), by striking out “Secretary of Health and Human Services” each place it occurs and inserting in lieu thereof “Administrator”, and

(6) by striking out “Secretary” each place it occurs except when followed by “of Agriculture” and inserting in lieu thereof “Administrator”.

(l) SECTION 412.—Section 412(h) (21 U.S.C. 350a(h)) is amended by striking out “(c)(1)(B),” and inserting in lieu thereof “(e)(1)(B)”.

(m) SECTION 502.—Section 502 (21 U.S.C. 352) is amended—

(1) in paragraph (e)(3), by striking out “: *Provided further*, That” and inserting in lieu thereof “, except that”,

(2) in paragraph (f), by striking out “: *Provided*, That” and inserting in lieu thereof “, except that”,

(3) in paragraph (g), by striking out “: *Provided*, That the method” and inserting in lieu thereof a period and “The method” and by striking out “: *Provided further*, That,” and inserting in lieu thereof “, except that”, and

(4) in paragraph (n), by striking out “: *Provided*, That” and inserting in lieu thereof “, except that”.

(n) SECTION 505.—Section 505 (21 U.S.C. 355) is amended—

(1) in subsection (j)(6)(A)—

(A) by striking out “Secretry” in clause (ii) and inserting in lieu thereof “Secretary”, and

(B) by inserting a comma after “Secretary” the first time it appears in clause (iii).

(2) in subsection (k)(1), by striking out “: *Provided, however*, That regulations” and inserting in lieu thereof a period and “Regulations”.

(o) SECTION 506.—Section 506(a) (21 U.S.C. 356(a)) is amended by striking out “Federal Security Administrator” and “Administrator” each place it appears and inserting in lieu thereof “Secretary”.

(p) SECTION 507.—Section 507 (21 U.S.C. 357) is amended—

(1) in subsection (a), by striking out “Federal Security Administrator” and “Administrator” each place it appears and inserting in lieu thereof “Secretary”,

(2) in subsection (e)—

(A) by striking out “section 507” each place it occurs and inserting in lieu thereof “this section”,

(B) by striking out “or 507” and inserting in lieu thereof “or this section”, and

(C) by striking out “: *Provided*, That, for purposes” and inserting in lieu thereof a period and “For purposes”,

(3) in subsection (g)(1), by striking out “: *Provided, however*, That regulations” and inserting in lieu thereof a period and “Regulations”, and

(4) in subsection (h), by striking out “507”.

(q) SECTION 508.—Subsections (c) and (e) of section 508 (21 U.S.C. 358) are each amended by striking out “section 4 of the Administrative Procedure Act (5 U.S.C. 1003)” and inserting in lieu thereof “section 553 of title 5, United States Code”.

(r) SECTION 512.—Section 512 (21 U.S.C. 360b) is amended—

(1) in subsection (c)(2)(A)(ii), by inserting “in” after “provided”,

(2) in subsection (c)(2)(F)(i), by striking out “(C)(iii)” and inserting in lieu thereof “(D)(iii)”,

(3) in subsection (c)(2)(H), by striking out “subclause” the first time it appears and inserting in lieu thereof “subclauses”,

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(4) in subsection (d)(1), by striking out “subparagraphs (A) through (G)” and inserting in lieu thereof “subparagraphs (A) through (I)”, and

(5) in subsection (n)(1)—

(A) by striking out “201(w)” in subparagraphs (B)(ii)(II) and (C)(ii)(I) and inserting in lieu thereof “201(v)”, and

(B) by striking out in the last sentence “(H)” and inserting in lieu thereof “(I)”.

(s) SECTION 513.—Section 513(b)(3) (21 U.S.C. 360c(b)(3)) is amended by striking out “5703(b)” and inserting in lieu thereof “5703”.

(t) SECTION 515.—Section 515(c)(2)(A) (21 U.S.C. 360e(c)(2)(A)) is amended by striking out “refer such application”.

(u) SECTION 519.—Section 519(a) (21 U.S.C. 360i(a)) is amended by striking out “paragraph (4)” and inserting in lieu thereof “paragraph (7)”.

(v) SECTION 527.—Section 527(b) (21 U.S.C. 360cc(b)) is amended—

(1) by striking out “507,,” and inserting in lieu thereof “507,”, and

(2) in paragraph (1), by striking out “The” and inserting in lieu thereof “the”.

(w) SECTION 534.—Section 534(f)(2) (21 U.S.C. 360kk) is amended by striking out “this Act” and inserting in lieu thereof “the Public Health Service Act”.

(x) SECTION 601.—Section 601(a) (21 U.S.C. 361) is amended by striking out “: *Provided*, That this” and inserting in lieu thereof “, except that this”.

(y) SECTION 701.—Section 701 (21 U.S.C. 371) is amended—

(1) in subsection (e)(1), by striking out the period after “Regulations)” the second time it occurs, and

(2) in subsection (f)(4), by striking out “sections 239 and 240 of the Judicial Code, as amended” and inserting in lieu thereof “section 1254 of title 28, United States Code”.

(z) SECTION 703.—Section 703 (21 U.S.C. 373) is amended—

(1) by striking out “: *Provided*, That” and inserting in lieu thereof “, except that”, and

(2) by striking out “: *Provided further*, That” and inserting in lieu thereof “, and except that”.

(aa) SECTION 704.—Section 704(a)(1) (21 U.S.C. 374(a)(1)) is amended—

(1) by striking out the semicolon after “materials” and inserting in lieu thereof a comma, and

(2) by striking out “(j)” the first time it appears and inserting in lieu thereof “(k)”.

(bb) SECTION 721.—Section 721(b)(5)(D) (21 U.S.C. 379e(b)(5)(D)) is amended by striking out “5703(b)” and inserting in lieu thereof “5703”.

(cc) SECTION 801.—Section 801(b) (21 U.S.C. 381(b)) is amended—

(1) by striking out “Administrator” the first time it occurs and inserting in lieu thereof “Secretary of Health and Human Services”,

(2) by striking out “Administrator” the second and third time it occurs and inserting in lieu thereof “Secretary”,

(3) by striking out “Administrator’s” and inserting in lieu thereof “Secretary’s”, and

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(4) by striking out “Federal Security Agency” and inserting in lieu thereof “Department of Health and Human Services”.
(dd) AGRICULTURE.—

(1) Sections 201(c), 201(d), 701(b), and 801(a) (21 U.S.C. 321(c), 321(d), 371(b), and 381(a)) are each amended by striking out “Agriculture” each place it appears and inserting in lieu thereof “Health and Human Services”.

(2) Sections 702(c) and 706 (21 U.S.C. 372(c) and 376) are each amended by striking out “of Agriculture” each place it appears.

SEC. 4. TECHNICAL AMENDMENTS TO AMENDATORY ACTS.

(a) SAFE MEDICAL DEVICES ACT OF 1990.—

(1) Section 18(b) of the Safe Medical Devices Act of 1990 (Public Law 101-629) is amended by striking out “(b)(4)(B)” and inserting in lieu thereof “(b)”, and

(2) Section 19(a)(4) of the Safe Medical Devices Act of 1990 (Public Law 101-629) is amended—

(A) by striking out “as amended by paragraphs (1) and (2)” and inserting in lieu thereof “as amended by paragraphs (1), (2), and (3)”,

(B) by striking out “530” and inserting in lieu thereof “531”, and

(C) by striking out “354” and inserting in lieu thereof “355”.

(b) MEDICAL DEVICE AMENDMENTS OF 1992.—Section 6(a) of the Medical Device Amendments of 1992 (Public Law 102-300) is amended by inserting “wherever appearing” after “‘any of its principal’ ”.

(c) NUTRITION LABELING AND EDUCATION ACT OF 1990.—Section 8 of the Nutrition Labeling and Education Act of 1990 is amended by striking the period at the end and inserting close quotation marks and a period.

Speaker of the House of Representatives.

*Vice President of the United States and
President of the Senate.*